

In re Reissue Application for U.S. Patent No.: 5,498,240

Inventors: Bagaoisan *et al.*

Serial No.: To be assigned

Filed: April 16, 1997

REISSUE APPLICATION TRANSMITTAL

For: INTRAVASCULAR CATHETER WITH A REPLACEABLE
SHAFT SECTION60854 U.S. PTO
08843711

04/16/97

The Assistant Commissioner of Patents
United States Patent and Trademark Office
Box Patent Application
Washington, D.C. 20231

SIR:

1. Transmitted herewith for filing is the above-identified reissue application

2. Enclosed are:

☒ the papers required for a filing date under 37 C.F.R. §1.17112 pages of specification including claims3 sheets of drawings☒ Other Specify: Return Receipt Postcard3. ☒ Please Prepare a Title Report for U.S. Patent No. 5,498,2404. ☒ Please Transfer Drawings from the File of U.S. Patent No. 5,498,2405. ☒ Applicant hereby offers to surrender the original patent, U.S. Patent No. 5,498,2406. ☐ Applicant is a small entity entitled to a 50% reduction in fees☐ Verified statement enclosed

7. Filing Fee Calculations

	Number in Original Patent	Number Extra Over Original Patent	Rate	Basic Filing Fee \$770.00
Total Claims	28 - 20 =	8	x \$22.00 =	\$176.00
Independent Claims	12 - 3 =	9	x \$80.00 =	\$720.00
Multiple dependent claims if any			x \$260.00 =	\$-0-

* If less than zero, enter "0".

Total Filing Fee \$1,666.00

8. Additional Fees

Title Report (37 C.F.R. §1.19(b)(4)) \$25.00

Other Specify \$-0-

Total Fees Due \$1,691.00

9. Fee Payment

☐ **Payment of filing fee deferred**☒ Attached is a check in the amount of \$ 1,691.00☐ Charge Deposit Account No.08-1641 in the amount of \$ _____. A duplicate of this request is attached.☒ The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 08-1641, referencing Docket No. 22965.2111By: Edward J. Lynch
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Reissue Application of

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5,498,240

on

INTRAVASCULAR CATHETER WITH A REPLACEABLE
SHAFT SECTION

Drawings: 3 Sheets
Docket No.: 22965.2111

HELLER, EHRMAN, WHITE & McAULIFFE

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eter from the patient's vasculature without loss of the distal position of the guidewire. The reason that it is important to maintain the position of the distal tip of the guidewire across the stenosis, is that, if the guidewire is withdrawn, it may
 5 take the attending physician a substantial amount of time, e.g. from about 15 minutes up to about two hours or more, to advance a replacement guidewire into the patient's coronary artery and across the stenosis to be dilated and to then advance the dilatation catheter until the dilatation balloon
 10 thereof crosses the stenotic region. The original unsuitable catheter is usually discarded.

In some instances, after a dilatation is complete, it is necessary or at least desirable to implant a stent in the dilated stenotic region to provide long term patency thereto.
 15 In these cases the dilatation catheter which has performed the dilatation is removed and another balloon catheter having an unexpanded stent mounted about the balloon is advanced over the in-place guidewire to the stenotic region where the balloon is inflated to expand and thus implant the
 20 stent in the stenotic region. In this case the original angioplasty catheter is also discarded.

What has been needed and heretofore unavailable is a system for easily changing a shaft section of an intravascular catheter without the need to discard the entire catheter. The
 25 present invention satisfies these and other needs

SUMMARY OF THE INVENTION

30 The present invention is directed to an intraluminal catheter with an exchangeable shaft section.

The intraluminal catheter of the invention has an elongated shaft having a proximal shaft section with at least one inner lumen extending therein and a distal shaft section with an inner lumen extending therein which is in communication
 35 with the inner lumen of the proximal shaft section. Means are provided to releasably secure the proximal end of the distal shaft section to the distal end of the proximal shaft portion. The proximal end of the distal shaft section is provided with releasable connecting means which is configured to be connected to connecting means on the distal
 40 end of the proximal shaft section which allows the distal section to be readily exchanged for another distal section. The preferred releasable connecting means are matching threads, male threads on the exterior of one shaft section
 45 member and female threads on the interior of another shaft section member which are configured to receive shaft section member with the male threads

In one aspect of the invention, the intraluminal catheter is a dilatation catheter for performing angioplasty procedures
 50 with a dilatation balloon on the distal shaft section thereof. This allows the original distal shaft section to be exchanged for another distal shaft section when, for example, the dilatation balloon is of inappropriate size, either in length or
 55 in inflated diameter, for a particular stenotic region of the patient's artery.

The distal shaft section 42 of the above dilatation catheter may also be replaced when it is necessary or desirable to
 60 instal a stent in a dilated stenotic region of the patient's artery to ensure that the region remains patent after the dilatation. In this case, the original distal shaft section is removed after the dilatation has been performed and a replacement distal shaft section having an inflatable balloon or other expandable means thereon with a stent mounted
 65 about the inflatable balloon or other expandable means. The catheter with the replacement distal shaft section is advanced within the arterial system of the patient until the

inflatable balloon or other expandable means is disposed within the stenosis so expansion thereof expands the stent to secure the stent within the arterial passageway. The expanded balloon may then be deflated and the catheter removed from the patient with the expanded stent maintaining within the arterial passageway to maintain its patency.

In a presently preferred embodiment, the exchangeable catheter shaft section has an inner and an outer tubular member with the threaded connections on an end of either the outer tubular member or the inner tubular member or both which engage the matching treads on the mating ends of the tubular members of the shaft section which is not to be replaced when the threaded connections are made.

The above described advantages of the invention as well as others will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view, partially in section, of an over-the-wire balloon dilatation catheter embodying features of the invention.

FIG. 2 is a transverse cross-sectional view of the catheter shown in FIG. 1 taken along the lines of 2—2

FIG. 3, is an elevational view, partially in section, of a rapid exchange type balloon dilatation catheter embodying features of the invention.

FIG. 4 is an elevational view of a distal portion of a balloon catheter embodying features of the invention with an expandable stent mounted on the balloon of the catheter with the balloon and the stent in expanded conditions within a stenotic region of a patient's artery

DETAILED DESCRIPTION OF THE INVENTION

With reference to FIGS 1 and 2, dilatation catheter 10 embodying features of the invention includes an elongated catheter shaft 11 with a proximal section 12 and a replaceable distal section 13. The proximal section 12 has an outer tubular member 14 and an inner tubular member 15 with the distal end of the outer tubular member having male threads 16 for connection to the distal section 13. The distal section 13 has an outer tubular member 17 and an inner tubular member 18 with proximal end of the outer tubular member 17 having female threads 19 which are configured to engage the male threads 16 on the distal end of the outer tubular member 14. The distal end of the inner tubular member 15 of the proximal section 12 is tapered so as to sealingly fit into the inner passageway of the inner tubular member 18 of the distal section 13 when the outer tubular members 14 and 16 are threadably connected (as shown in phantom in FIG 1). The outer tubular member 17 may be provided with webs or spacers (not shown) to centrally position the inner tubular member 18 within the outer tubular member 17 to ensure appropriate entry of the distal end of the inner tubular member 15 into the inner tubular member 18.

A dilatation balloon 22 is provided on the replaceable distal section 13 which has an interior in fluid communication with the annular inner lumen 23 defined between the inner and outer tubular members 18 and 17 and the annular lumen 24 defined between the outer and inner tubular members 14 and 15 of the proximal section 12.

A multiarm adaptor 25 is provided on the proximal end of the proximal section 12 to facilitate delivery of inflation fluid to the interior of dilatation balloon 22 through side arm 26 and annular lumens 23 and 24. The inner tubular members 15 and 18 define a guidewire receiving lumen 27 which extends from the adaptor 25 through the length of the catheter to a distal guidewire port 28 in the distal end of the distal placeable section 13 and is configured to slidably receive a guidewire 30.

Due to strength requirements for the threaded connection between the outer tubular members 14 and 17, it is usually preferable to form the threaded portions 31 and 32 of these members of a high strength material (e.g. stainless steel, NiTi alloys and the like). In this instance, the separate threaded connecting elements 31 and 32 would be formed independently of the other portions of the outer tubular members 14 and 17 and then secured to these members by a suitable adhesive or other means such as a fusion or solvent bond, depending upon the nature of the material from which the separate connecting elements 31 and 32 are formed. Other materials which are suitable for forming the connecting elements 31 and 32 include high strength polymers such as polycarbonate polymers and the like.

The dilatation catheter 10 depicted in FIGS. 1-2 may be used in a typical fashion whereby it is advanced over guidewire 30 previously disposed across the stenosis to be dilated until the balloon 22 extends across the lesion to be dilated. In the event the balloon's size, e.g. its inflated diameter or its length, is found to be inappropriate for the lesion to be dilated, the catheter 10 is withdrawn from the patient over the guidewire 30 and once outside of the patient, the removable distal section 13 and the proximal section 12 can be separated by twisting one or both so that the threaded members 31 and 32 can disengage. Another distal section of essentially the same construction, but with a balloon with a more appropriately sized length or inflated diameter, may then be threadably secured onto the distal end of the proximal section 12 and the reconstructed dilatation catheter may then be mounted onto the in-place guidewire and advanced over the guidewire until the more appropriately sized dilatation balloon crosses the stenosis. An extension wire is usually secured to the proximal end of the guidewire 30 to facilitate the withdrawal of the original catheter 10 and the introduction and advancement of the replacement catheter with a new distal shaft section through the patient's arterial system until the more appropriately sized replacement balloon extends across the stenosis. The replacement balloon may then be inflated one or more times in a conventional manner to dilate the stenotic region of the patient's artery and then be withdrawn as the original catheter 10.

FIG. 3 illustrates a rapid exchange type dilatation catheter 40 embodying features of the invention which has a proximal shaft section 41, a distal shaft section 42, a dilatation balloon 43 on the distal shaft section and an adaptor 44 on the proximal end of the proximal shaft section. The proximal shaft section 41 is preferably hypotubing formed of metal such as stainless steel (e.g. 304) or pseudoelastic NiTi alloy provided with male threads 46 which are configured to threadably engage the female threads 47 on connector element 48 secured to the proximal end of distal shaft section 42. As shown in FIG. 3, the distal shaft section 42 is provided with a guidewire receiving inner lumen 50 which extends from proximal guidewire port 51 to the distal guidewire port 52 provided in the distal end of the catheter. A dual lumen portion 53 extends from the connector element 48 to just within the proximal end of the balloon 43 and a tubular extension 54 thereof extends through the interior of

the balloon 43 and out the distal end thereof. A guidewire 55 is slidably disposed within the guidewire receiving inner lumen 50. A radiopaque marker 56 is provided on the tubular extension 54 at the midpoint between the two ends of the balloon 43 to facilitate the fluoroscopic observation thereof within the patient.

The distal shaft section 42 of the catheter 40 may be replaced as in the previously described embodiment, the only major difference being that there is no need for an extension wire to facilitate withdrawal of the original catheter 40 and the introduction of the replacement catheter with a different distal section.

FIG. 4 illustrates a replacement distal section 60 similar to the distal section 42 shown in FIG. 3 but adapted to deliver an expandable stent 61 to a stenotic region of a patient's artery to provide long term patency. Once the stent 61 is properly expanded, the balloon 63 may be deflated and the catheter withdrawn from the patient. This particular embodiment may be utilized after dilatation of the stenotic region by means of a catheter of the invention such as shown in FIG. 3. In this instance, after the dilatation, the dilatation catheter may be withdrawn, the distal section 42 removed from the proximal shaft section 41 by disengaging the threaded ends of the proximal shaft section and connector element 48 and securing the replacement distal section 60 to the threaded end of proximal shaft section by threadably engaging the connector element 64 with female threads 65 to the distal end of the proximal shaft section with male threads 46. The replacement catheter with the distal section 60 may then be advanced into and through the patient's arterial system over the guidewire 66 until the balloon 63 is disposed across the stenosis. Expansion of the balloon 63 within the stenosis expands the stent 61 to hold open the stenotic region of the patient's artery. The catheter can then be removed with the stent remaining within the dilated arterial passageway to maintain its patency.

The catheter construction and the materials of the various portions thereof may be conventional. Moreover, while the invention is described herein in terms of certain preferred embodiments, a variety of modification can be made. For example, threaded connections are described between the proximal and distal shaft sections to facilitate separation of the distal shaft section from the proximal shaft section. However, other types of connections are contemplated with the present invention, the threaded connection being a presently preferred embodiment. Other connections include projections and corresponding detents. Additionally, while replacement of the distal shaft section is primarily described herein, those skilled in the art will recognize that the proximal shaft section may be the replaceable shaft section. Other modifications and improvements may be made to the invention without departing from the scope thereof.

What is claimed is

1. An intravascular catheter with an exchangeable shaft section, comprising:

- a) an elongated tubular proximal shaft section having proximal and distal ends and a first inner lumen extending therein,
- b) an elongated distal shaft section having proximal and distal ends, a port in the distal end of the distal shaft section, a second inner lumen extending therein in fluid communication with the first inner lumen in the proximal shaft section and a third inner lumen which is configured to slidably receive a guidewire and which extends therein to the port in the distal end of the distal shaft section, and

c) means to releasably interconnect the distal end of the proximal shaft section and the proximal end of the distal shaft section to effect fluid communication between the first and second inner lumens.

5 2. The intravascular catheter of claim 1 wherein an inflatable dilatation balloon is provided on the distal shaft section having an interior in fluid communication with the second inner lumen in the distal section.

10 3. The intravascular catheter of claim 1 wherein the connector means includes male threads on an end of one of the shaft sections and female threads on a mating end of the other shaft section which are configured to threadably engage the male threads

15 4. The intravascular catheter of claim 1 wherein the tubular proximal shaft section includes an inner tubular member disposed therein which has a fourth inner lumen which is configured to slidably receive a guidewire therein and which is in communication with the third inner lumen in the distal shaft section.

20 5. The intravascular catheter of claim 2 wherein means are provided on the proximal end of the proximal section for directing fluid through the first inner lumen extending therein and the second inner lumen in the distal section into the interior of the balloon.

25 6. A dilatation catheter with an exchangeable shaft section, comprising:

a) an elongated proximal shaft section having proximal and distal ends and an first inner lumen extending therein to the distal end;

30 b) an elongated distal shaft section having proximal and distal ends, a second inner lumen extending from the proximal end of the distal shaft section to a location spaced proximally from the distal end of the distal shaft section, a distal port in the distal end, a third inner lumen extending therein to and being in fluid communication with the distal port and being coextensive and parallel with at least part of the second inner lumen,

35 c) means to releasably connect the distal end of the proximal shaft section to the proximal end of the distal shaft section to effect fluid communication between the first inner lumen of the proximal shaft section and the second inner lumen of the distal shaft section; and

40 d) an inflatable dilatation balloon on the distal shaft section having an interior in fluid communication with the second inner lumen

45 7 The dilatation catheter of claim 6 wherein the connecting means include male threads on an end of one of the shaft sections and matching female threads on a mating end of the other shaft section

50 8. The dilatation catheter of claim 7 wherein the proximal shaft section includes inner and outer tubular members, the distal shaft section includes inner and outer tubular members and the threaded connecting means are on mating ends of the inner tubular members of the proximal and distal shaft sections.

55 9 The dilatation catheter of claim 7 wherein the proximal shaft section includes inner and outer tubular members, the distal shaft section includes inner and outer tubular members and the threaded connecting means are on mating ends of the outer tubular members of the proximal and distal shaft sections

60 10. A balloon catheter with an exchangeable shaft section, comprising:

65 a) an elongated proximal shaft section having proximal and distal ends and an first inner lumen extending therein to the distal end,

- b) an elongated distal shaft section having proximal and distal ends, a second inner lumen extending from the proximal end of the distal shaft section to a location spaced proximally from the distal end of the distal shaft section, a distal port in the distal end of the distal shaft section, a third inner lumen extending within the distal shaft section to the distal port and a third inner lumen extending therein coextensive and parallel with at least part of the second inner lumen and being in fluid communication with the distal port;
- c) means to releasably connect the distal end of the proximal shaft section and the proximal end of the distal shaft section to effect fluid communication between the first inner lumen of the proximal shaft section and the second inner lumen of the distal shaft section; and
- d) an inflatable balloon on the distal shaft section having an interior in fluid communication with the second inner lumen.

11. The balloon catheter of claim 10 including an expandable stent which is mounted about the inflatable balloon in an uninflated condition and which is configured to expand upon the inflation of the balloon.

12. A method of treating a patient's body lumen, comprising:

- a) providing an intraluminal catheter which has an elongated catheter shaft, a proximal shaft section, a replaceable distal shaft section and means to releasably connect the replaceable distal section with the proximal shaft section;
- b) advancing the intraluminal catheter through a patient's body lumen until the catheter is disposed within a desired region thereof;
- c) performing an intraluminal procedure within the body lumen with the intraluminal catheter;
- d) withdrawing the intraluminal catheter from the patient;
- e) removing the replaceable distal shaft section of the intraluminal catheter;
- f) connecting a replacement distal shaft section to the proximal shaft section, and
- g) advancing the intraluminal catheter with the replacement distal shaft section into the patient's body lumen until the intraluminal catheter is disposed within a desired region of the patient's body lumen.

13. A method of treating a patient's body lumen, comprising:

- a) providing a dilatation catheter which has an elongated catheter shaft, a replaceable distal shaft section, a dilatation balloon on the replaceable distal shaft section, a proximal shaft portion and means to connect the proximal and distal shaft sections;
 - b) advancing the dilatation catheter through the patient's vasculature until the dilatation balloon is disposed within a stenotic region of a patient's artery;
 - c) withdrawing the dilatation catheter from the patient;
 - d) removing the replaceable distal shaft section of the catheter, and
 - e) connecting a replacement distal shaft section to the proximal shaft section, and
- advancing the catheter with the replacement distal shaft section into the patient's vasculature until the catheter

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is disposed within a desired region of the patient's vasculature

14. The method of claim 13 wherein the replacement distal shaft section has an inflatable balloon with an expandable stent mounted about the inflatable balloon and when the inflatable balloon and stent mounted thereon are disposed within the desired region of the patient's vasculature, inflating the balloon to expand the stent within the desired region of the vasculature and then deflating the balloon so that the catheter can be removed, leaving the expanded stent within the patient's vasculature.

15. A dilatation catheter comprising:

- a) an elongated catheter shaft having proximal and distal ends, a guidewire port in the distal end, a guidewire receiving inner lumen extending to and being in fluid communication with the guidewire port and an inflation lumen extending to location proximal to the distal end;
 - b) a proximal shaft section having proximal and distal ends and at least part of the inflation lumen extending therein to the distal end of the proximal shaft section; and
 - c) a replaceable distal shaft section having a proximal end, being releasably connected by said proximal end of the distal shaft section to the distal end of the proximal shaft section, at least part of the inflation lumen extending within the distal shaft section distally therein from the proximal end of the distal shaft section to the location proximal to the distal end of the catheter shaft, and
 - d) a dilatation balloon on the distal shaft section surrounding the location having an interior in fluid communication with the portion of the inflation lumen extending within the distal shaft section
16. An intravascular catheter comprising:
- a) a proximal shaft section having a proximal end, a distal end and an inner lumen extending therein;
 - b) a distal shaft section having a proximal end, a distal end, a port in the distal end, a second inner lumen extending therein in fluid communication with the inner lumen of the proximal shaft section and a third inner lumen extending parallel and at least partially coextensive with the second inner lumen within the distal shaft section and in fluid communication with the port in the distal end of the distal shaft section, and
 - c) means to releasably connect the proximal end to the distal shaft section to the distal end of the proximal shaft section

17. The intravascular catheter of claim 16 wherein the distal shaft section is releasably connected to the proximal shaft section by means of interconnecting threads on the distal end of the proximal shaft section and on the proximal end of the distal shaft section.

18. The intravascular catheter of claim 17 wherein the threads on the distal end of the proximal shaft section are male threads and the mating threads on the proximal end of the distal section are female threads.

19. The intravascular catheter of claim 17 wherein the proximal section is a metallic tube.

20. The intravascular catheter of claim 19 wherein the metallic proximal shaft section has male threads on the distal end thereof.

21. The intravascular catheter of claim 17 wherein the means to releasably connect the proximal end of the distal

shaft section to the distal end of the proximal shaft section includes an intermediate tubular element which has proximal and distal ends, threads on at least one of said ends which match the threads on the mating end of one of the shaft sections with the other of said ends of the intermediate tubular element being secured to the mating end of the other shaft section.

22. The intravascular catheter of claim 21 wherein threads are on the proximal end of the intermediate tubular element and the distal end of the proximal shaft section.

23. The intravascular catheter of claim 21 wherein threads are on the distal end of the intermediate tubular element and the proximal end of the distal shaft section.

* * * * *

24. A method for performing a medical procedure using a catheter comprising the steps of:

- a) providing a catheter with a first catheter shaft section having a proximal end, a distal end and a first inner lumen extending therein to a location proximal to the distal end, a second catheter shaft section disposed proximal to the first catheter shaft section having a proximal end, a distal end and an inner lumen extending therein and a releasable connection between the distal end of the second catheter shaft section and the first catheter shaft section with the inner lumen within the first shaft section being in fluid communication with the inner lumen within the second catheter shaft section;
- b) inserting the catheter into a patient over a guidewire disposed in part within the patient, with at least a portion of the second catheter shaft section extending out of the patient, to perform a medical procedure;
- c) pulling the portion of the second shaft section extending out of the patient over the guidewire to withdraw at least part of the catheter shaft from the patient; and
- d) disengaging one of the catheter shaft sections from the other catheter shaft section.

25. An intravascular catheter which comprises proximal and distal ends, a port in the distal end, a balloon connected to an inflation lumen, said balloon being carried adjacent said distal end, a guidewire lumen extending within the catheter to the port in the distal end, said catheter comprising a plurality of segments having connectors which are secured together in end-to-end relations to form said catheter, but which are both separable into separated segments by the user.

26. The method of removing an intravascular catheter from a patient's vascular system over a guidewire, which comprises: grasping said catheter and grasping said guidewire; partially withdrawing said catheter out of the vascular system of the patient while restraining the guidewire from retracting movement; removing a proximally mounted section of said catheter from the remainder of said catheter, and separately sliding said catheter section off of the guidewire while substantially continuously grasping the guidewire to prevent retracting movement thereof.

27. A method for withdrawing a catheter from a patient's vascular system, which comprises the steps of:

a) introducing a guidewire into said vascular system;

b) advancing a catheter in said vascular system over said guidewire,
said catheter having at least a distal section and a proximal section releasably
connected to the distal section;

c) withdrawing said catheter from said vascular system over said
guidewire by first removing said proximal section while restraining said
guidewire; and

d) thereafter removing said distal section while restraining said
guidewire.

28. A catheter for introduction into and withdrawal from the vascular
system of a patient over a guidewire in said vascular system, which comprises:

a) said catheter having a distal section and a proximal section;

b) said distal section and said proximal section being
alternatively connectable and separable; and

c) said catheter being adapted for introduction into said
vascular system over said guidewire and for withdrawal from said vascular
system over said guidewire by removing said proximal section while restraining
said guidewire and thereafter removing said distal section while restraining said
guidewire.

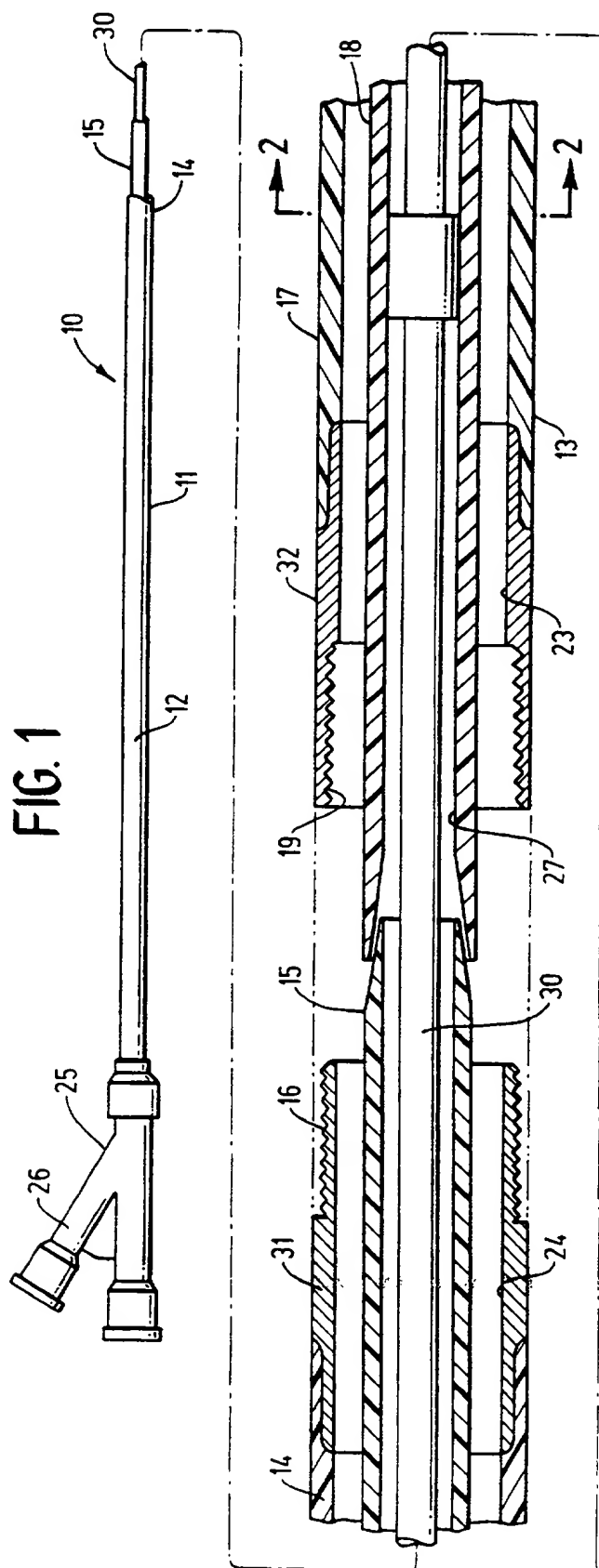
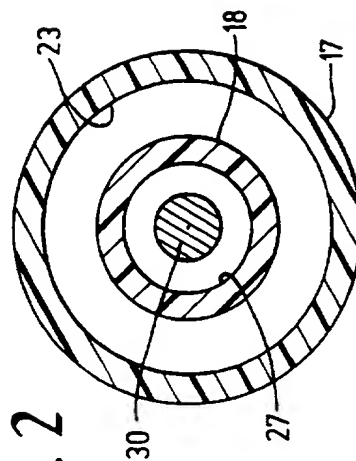
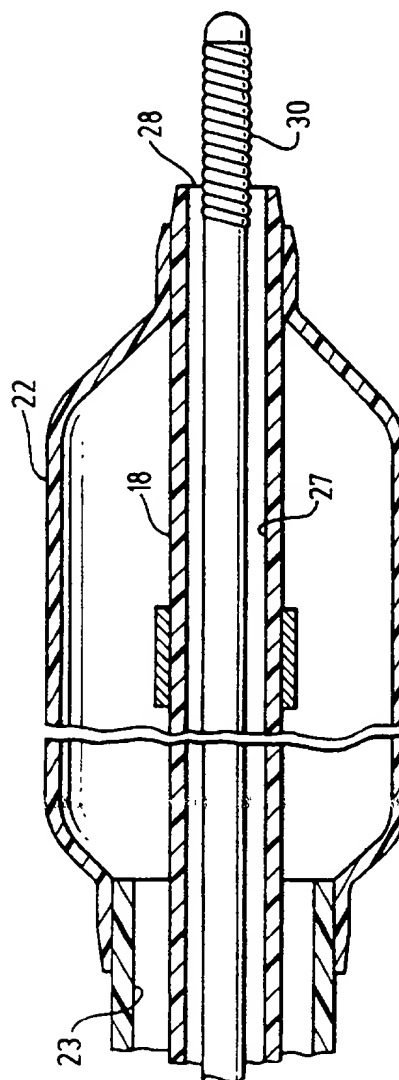
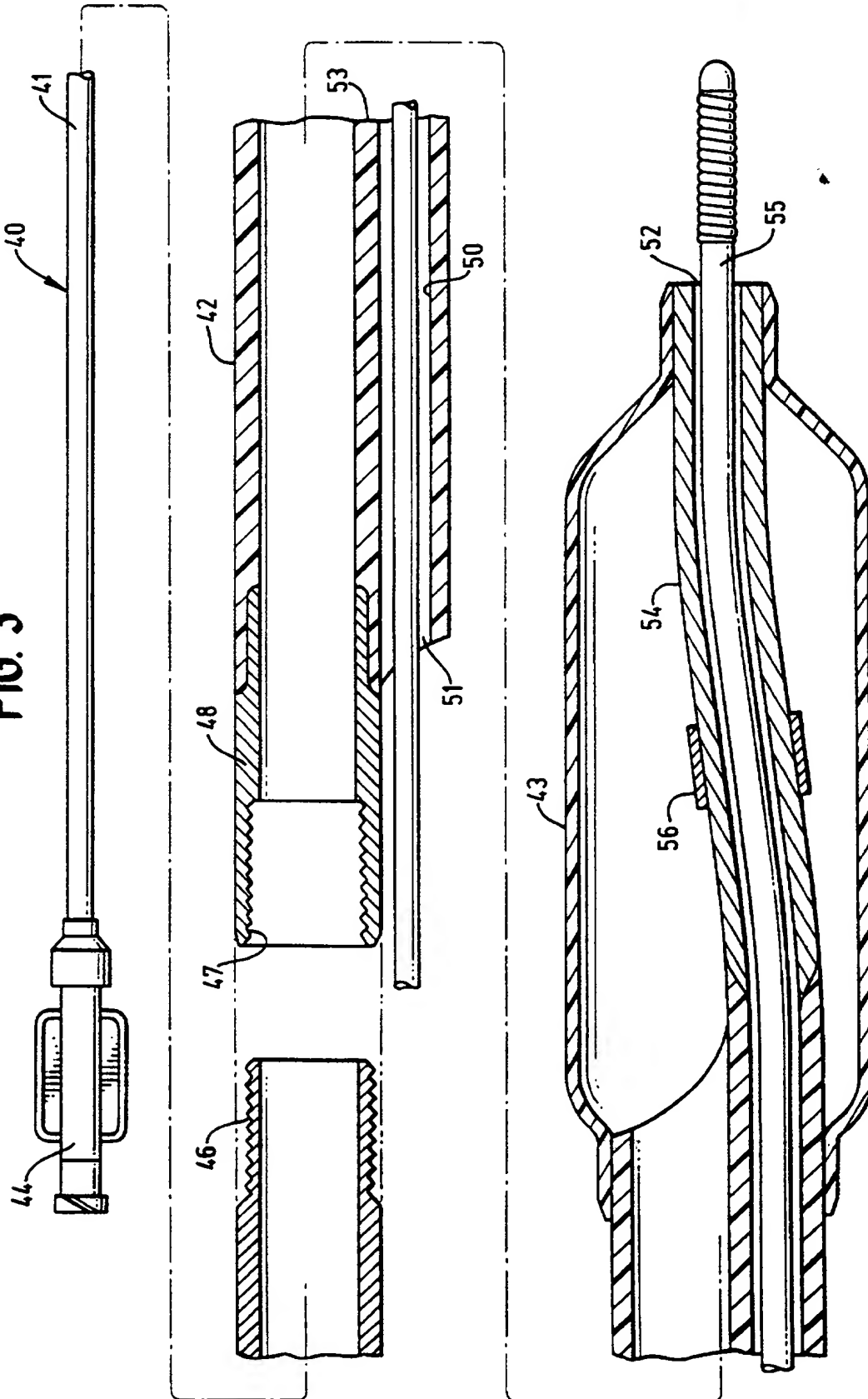


FIG. 2



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FIG. 3



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FIG. 4

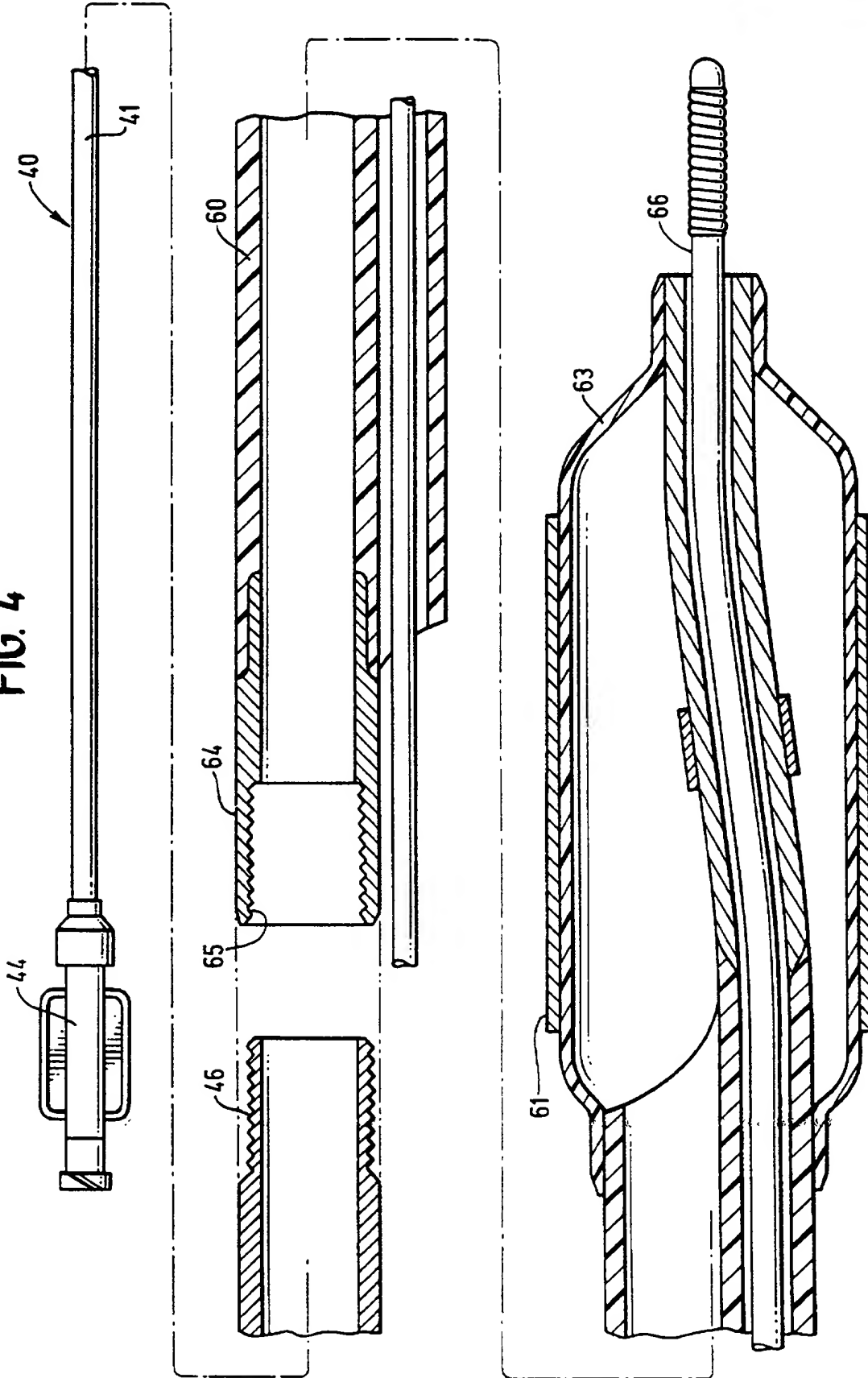


EXHIBIT A

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FROM:	REFERENCE NUMBER	NUMBER OF PAGES	DATE
Nita J. Miller	22965-2111	1 (including cover page)	January 29, 1998

MESSAGE:

Further to my January 5, 1997, letter regarding the Reissue Application, entitled INTRAVASCULAR CATHETER WITH REPLACEABLE SHAFT SECTION, please be advised that today is the final deadline to file the Declaration and Power of Attorney with the Patent office.

Please contact me as soon as you receive this facsimile at (650) 324-7107, or simply send me the signature page of the Declaration via facsimile at the number referenced above.

Should you have any questions, please feel free to contact me. Thank you.

Yours truly,

Nita

65065.01.PA (1#7D011.DOC)
01/29/98 7:03 PM

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0309

REISSUE

#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S.

Examiner: Not yet assigned

Patent No.: 5,498,240

Group Art Unit: 3306

Issued: September 10, 1996

Docket No.: 22965-2111

Inventors: Bagaoisan *et al.*

Serial No.: 08/843,711

Filed: April 16, 1997

For: **INTRAVASCULAR CATHETER WITH
A REPLACEABLE SHAFT SECTION****RESPONSE TO NOTICE TO FILE
MISSING PARTS OF APPLICATION**

BOX MISSING PARTS

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Notice to File Missing Parts of Application - Filing Date Granted mailed July 29, 1997, transmitted herewith is Part 2 of the Notice to File Missing Parts of Application - Filing Date Granted; Declaration and Power of Attorney; Petition for Filing By Other Than All Inventors, under 37 C.F.R. § 1.47(a); Declaration of Nita Miller; Assent of Assignee to Reissue Application; and a return postcard.

Applicant is other than a small entity. Applicant hereby petitions for an Extension of Time of four (4) months, pursuant to 37 C.F.R. § 1.136(a).

Payment of Fees. Please charge the following fees to Deposit Account No. 08-1641, referencing Docket No. 22965-2111. The Commissioner is authorized to charge any additional fees and credit any overpayment which may be required in connection with this application to Deposit Account No. 08-1641, referencing Docket No. 22965-2111.

Extension Fee under 37 C.F.R. § 1.17(d)	\$1,510.00
Surcharge fee under 37 C.F.R. § 1.27	130.00
Petition Fee under 37 C.F.R. § 1.17(h)	130.00
TOTAL FEES:	\$1,770.00

Respectfully submitted,

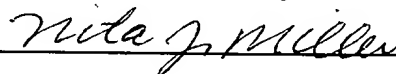
By: William B. Anderson
Reg. No. P41,585

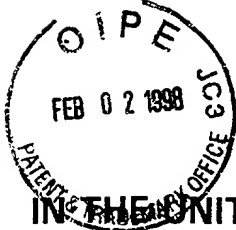
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EJL:PM:njm

CERTIFICATE OF MAILING

I hereby certify that these papers are being deposited in the U.S. mail as first class with postage prepaid, addressed to: BOX MISSING PARTS, Assistant Commissioner for Patents, Washington D.C. 20231, on January 29, 1998, in Palo Alto, CA.





REISSUE

#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for)	Examiner: Not yet assigned
)	
Patent No.: 5,498,240)	Group Art Unit: 3306
)	
Issued: September 10, 1996)	
)	
Inventors: Bagaoisan, <i>et al.</i>)	
)	
Serial No.: 08/843,711)	
)	
For: INTRAVASCULAR CATHETER WITH)	
A REPLACEABLE SHAFT SECTION)	
)	
Filed: April 16, 1997)	
)	
Docket No.: 22965.2111)	

DECLARATION PURSUANT TO 37 C.F.R. § 1.175
AND POWER OF ATTORNEY

Assistant Commissioner for Patents
BOX REISSUE
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

I depose and say that:

1. My residence, post office address and citizenship is as stated below
next to my name.

2. I believe that I am an original, first and joint inventor of the subject matter which is claimed and for which a patent on the invention entitled **INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION**, was granted on March 12, 1996 as U.S. Patent No. 5,498,240 ('240 patent), a copy of which is attached as Exhibit A.

3. I have reviewed and understand the contents of the specification of the '240 patent, including the claims.

4. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

5. I believe the '240 patent to be partly inoperative or invalid because of error without any deceptive intent on the part of the applicants, by reason of the fact that we claimed less than we had the right to claim in the original patent.

6. I believe that during prosecution of the application, the attorney handling the prosecution failed to claim aspects of the invention which we are entitled to claim. Claims 1, 6 and 12 of the '240 patent are unduly limited in several aspects, and claim 12 lacks certain desirable clarifying language which would effectively broaden the scope of the claim.

7. The invention is directed to a catheter having one or more exchangeable shaft sections, and a method of using the catheter. Claims 1, 6 and 12 have limitations which unnecessarily limit the scope of the invention claimed.

8. Claims 1 and 6 of the '240 patent are now unnecessarily limited to a catheter with an exchangeable shaft section and claim 12 is limited to a replaceable distal shaft section, whereas the invention disclosed in the patent includes exchangeable distal and proximal shaft sections.

9. Claim 6 has limitations which unnecessarily limit the scope of the invention claimed. Claim 6 now is limited to a dilatation catheter, whereas the catheter construction disclosed in the patent and contemplated by the invention is more broadly directed to an intravascular catheter.

10. Claim 12 has limitations which may unnecessarily limit the scope of the invention claimed. Claim 12 now is limited to treating a patient's body lumen, whereas the method disclosed in the patent is more broadly directed to a method of performing a medical procedure. Claim 12 requires removing the replaceable distal shaft section, and connecting a replacement distal shaft section to the proximal shaft section. The method disclosed in the patent broadly involved separating connected shaft sections and does not require connecting a replacement distal shaft section.

11. Claim 12 lacks clarifying language, namely, that the catheter is slid on and off a guidewire while the guidewire is restrained, and that the whole catheter is not withdrawn from the patient before the catheter shaft sections are separated.

12. On information and belief, the attorney handling the prosecution of the original application, Edward J. Lynch, through error without deceptive intent, failed to recognize the above described features of the invention in their broadest sense.

13. I am unaware how or when the error occurred but, on information and belief I believe that it occurred during the prosecution of the original application.

14. On information and belief, Edward J. Lynch, undertook a review of the '240 patent during the first quarter of 1997 and, as a result of his review, he concluded that he did not appreciate the breadth of the invention when he was prosecuting the original application.

15. On information and belief, as a result of Mr. Lynch's review, he recommended to the assignee, Advanced Cardiovascular Systems, Inc., that a reissue application be filed for the '240 patent within two years from the issue date thereof, so that the invention thereof could be claimed more broadly.

16. I have reviewed the new claims 24-28 which are included with the present reissue application as filed and new claims 29 and 30 which are presented by preliminary amendment, copies of which are attached hereto as Exhibit B, and believe that we were entitled to claim the invention set forth in these claims 24-30 at the time the original application for the above-referenced patent was made.

17. I hereby appoint the following attorneys and agents to prosecute this reissue application and to transact all business in the United States Patent and Trademark Office connected therewith:

EDWARD J. LYNCH, Registration No. 24,422
ALAN M. KRUBINER, Registration No. 26,289
WILLIAM SCHMONSEES, Registration No. 31,796
JACQUES DULIN, Registration No. 24,067
HERWIG von MORZE, Registration No. 29,484
WALTER KURZ, Registration No. 37,373
DEREK P. FREYBERG, Registration No. 29,250
PING CHOW, Registration No. 30,740
ROBERT DENNIS, Registration No. 40,988

of the firm

HELLER EHRMAN WHITE & McAULIFFE
525 University Avenue
Palo Alto, CA 94301-1900
(650) 324-7000

and

COLIN D. BARNITZ, Registration No. 35,061
WILLIAM A. BLAKE, Registration No. 30,548
GEORGE M. COOPER, Registration No. 20,201
FELIX J. D'AMBROSIO, Registration No. 25,721
DOUGLAS R. HANSCOM, Registration No. 26,600
JIM W. HELLWEGE, Registration No. 28,808
ERIC S. SPECTOR, Registration No. 22,495

of the firm:

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Telephone: (703) 415-1500

Direct all correspondence to:

Edward J. Lynch
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525 University Avenue
Palo Alto, CA 94301-1900
Tel. No.: (650) 324-7000
Direct Dial: (650) 324-7098
Facsimile: (650) 324-0638

I hereby declare that all statements made herein of my own knowledge
are true and that all statements made on information and belief are believed to be
true; and further that these statements were made with the knowledge that willful

false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of First Inventor: Celso S. J. Bagaoisan

Executed on ___ day of _____, 19__.

Inventor's Signature: _____

Residence: 4441 Pomponi Street, Union City, California 94587

Post Office Address: same as above

Citizenship: United States of America

Full name of Second Inventor: John P. Shanahan

Executed on ___ day of _____, 19__.

Inventor's Signature: _____

Residence: 61 Leigh Hill Road, Cobham Surrey, KT112HY, UK

Post Office Address: same as above

Citizenship: United States of America

Full name of Third Inventor: Ketan P. Muni

Executed on 6th day of January, 1978

Inventor's Signature: Ketan P. Muni

Residence: 97 Frontier Trail Drive, San Jose, CA 95136

Post Office Address: same as above

Citizenship: India U.S.A.

Full name of Fourth Inventor: Elizabeth N. Hammack

Executed on ___ day of ___, 19__.

Inventor's Signature _____

Residence: 12781 W. Sunset Hills Drive, Los Altos Hills, CA 94022

Post Office Address: same as above

Citizenship: United States of America

Full name of Fifth Inventor: Robert M. Abrams

Executed on ___ day of ___, 19__.

Inventor's Signature _____

Residence: 359 Redondo Terrace, Sunnyvale, CA 94086

Post Office Address: same as above

Citizenship: United States of America

Full name of Sixth Inventor: James C. Peacock, III

Executed on ___ day of ___, 19__.

Inventor's Signature _____

Residence: 526 East Evelyn Avenue, Sunnyvale, CA 94086

Post Office Address: same as above

Citizenship: United States of America

Full name of Seventh Inventor: William S. Tremulis

Executed on 29 day of January, 1998

Inventor's Signature _____

Residence: 97 Pelican Lane, Redwood City, CA 94065

Post Office Address: same as above

Citizenship: United States of America

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Full name of Fourth Inventor: Elizabeth N. Hammack

Executed on ___ day of _____, 19__.

Inventor's Signature _____

Residence: 12781 W. Sunset Hills Drive, Los Altos Hills, CA 94022

Post Office Address: same as above

Citizenship: United States of America

Full name of Fifth Inventor: Robert M. Abrams

Executed on 6 day of JANUARY, 1998.

Inventor's Signature: 

Residence: 359 Redondo Terrace, Sunnyvale, CA 94086

Post Office Address: same as above

Citizenship: United States of America

Full name of Sixth Inventor: James C. Peacock, III

Executed on ___ day of _____, 19__.

Inventor's Signature: _____

Residence: 526 East Evelyn Avenue, Sunnyvale, CA 94086

Post Office Address: same as above

Citizenship: United States of America

Full name of Seventh Inventor: William S. Tremulis

Executed on ___ day of _____, 19__.

Inventor's Signature _____

Residence: 97 Pelican Lane, Redwood City, CA 94065

Post Office Address: same as above

Citizenship: United States of America

Full name of Fourth Inventor: Elizabeth N. Hammack

Executed on 6 day of January, 1998.

Inventor's Signature

Elizabeth N. Hammack

Residence:

12781 W. Sunset Hills Drive, Los Altos Hills, CA 94022

Post Office Address:

same as above

Citizenship:

United States of America

Full name of Fifth Inventor: Robert M. Abrams

Executed on ___ day of _____, 19__.

Inventor's Signature:

Residence:

359 Redondo Terrace, Sunnyvale, CA 94086

Post Office Address:

same as above

Citizenship:

United States of America

Full name of Sixth Inventor: James C. Peacock, III

Executed on ___ day of _____, 19__.

Inventor's Signature:

Residence:

526 East Evelyn Avenue, Sunnyvale, CA 94086

Post Office Address:

same as above

Citizenship:

United States of America

Full name of Seventh Inventor: William S. Tremulis

Executed on ___ day of _____, 19__.

Inventor's Signature

Residence:

97 Pelican Lane, Redwood City, CA 94065

Post Office Address:

same as above

Citizenship:

United States of America

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S.) Examiner: Not yet assigned
)
Patent No.: 5,498,240) Group Art Unit: 3306
Issued: September 10, 1996)
) Docket No.: 22965-2111
Inventors: Bagaoisan et al.)
)
Serial No.: 08/843,711)
Filed: April 16, 1997)
)
For: INTRAVASCULAR CATHETER WITH)
A REPLACEABLE SHAFT SECTION)

**PETITION FOR FILING BY OTHER THAN ALL
INVENTORS PURSUANT TO 37 C.F.R. § 1.47(a)**

BOX MISSING PARTS

Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

Applicant hereby petitions for acceptance of the declarations of signing joint inventors Ketan P. Muni, Elizabeth N. Hammack, Robert M. Abrams, and William S. Tremulis on behalf of all joint inventors: Celso S. J. Bagaoisan, John P. Shanahan, Ketan P. Muni, Elizabeth N. Hammack, Robert M. Abrams, James C. Peacock III, and William S. Tremulis, with the aforementioned signing joint inventors declaring on behalf of the non-signing inventors pursuant to MPEP 409.03(a). This petition is made for the reason that after diligent effort to obtain the declarations of Celso S. J. Bagaoisan, John P. Shanahan, and James C. Peacock III, counsel for applicants was unable to obtain said declarations. On various dates from January 5, 1998 to January 7, 1998, assistant to applicant's counsel, Nita J. Miller, forwarded by Federal Express a request for declaration to all joint inventors at their respective last know addresses. As of the time of the filing of this petition, no response has been received from the non-signing joint inventors, Celso S. J. Bagaoisan, John P. Shanahan, and James C. Peacock III. Filed with and in support of this petition is the declaration of Nita J. Miller regarding the facts

surrounding the unavailability of the aforementioned inventors, and a list of the last known addresses of the unavailable inventors below.

Last known addresses and telephone numbers of non-signing joint inventors:

Celso S. J. Bagaoisan
4441 Pomponi Street
Union City, California 94587
(510) 471-0747

John P. Shanahan
1530 Barn Owl Place
Santa Rosa, CA 95409
(707) 579-2620

James C. Peacock, III
526 East Evelyn Avenue
Sunnyvale, CA 94086
(408) 245-9427

Respectfully submitted,

By:



William B. Anderson
Attorney for Applicants
Registration No. P41,585

HELLER EHRMAN WHITE & McAULIFFE
525 University Avenue
Palo Alto, CA 94301-1900
Direct Dial: (650) 324-7127
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

WBA:njm

HEWM #65074

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S.)	Examiner: Not yet assigned
)	
Patent No.: 5,498,240)	Group Art Unit: 3306
Issued: September 10, 1996)	
)	Docket No.: 22965-2111
Inventors: Bagaoisan <i>et al.</i>)	
)	
Serial No.: 08/843,711)	
Filed: April 16, 1997)	
)	
For: INTRAVASCULAR CATHETER)	
WITH A REPLACEABLE SHAFT SECTION)	

**DECLARATION OF NITA J. MILLER IN SUPPORT OF PETITION FOR FILING BY
OTHER THAN ALL INVENTORS PURSUANT TO 37 C.F.R. § 1.47(e)**

BOX MISSING PARTS

Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

I, Nita J. Miller, depose and say that:

1. I have been a Patent Assistant to Edward J. Lynch, Applicants' Attorney, with HELLER EHRMAN WHITE & MCAULIFFE since July 1997. However, I have been employed as a Patent Assistant since October 1991.

2. On January 5, 1998, I forwarded a letter to James C. Peacock, III, via Federal Express, to 526 East Evelyn Avenue, Sunnyvale, CA 94086. I enclosed therewith a Declaration and Power of Attorney for his signature in connection with the above-referenced matter, and a return self-addressed, postage prepaid Federal Express envelope. A copy of said letter is attached hereto as Exhibit A. On January 29, 1998, I telephoned James Peacock, III at his residence (408) 245-9427, however, his listed telephone number was being forwarded to a facsimile machine. On January 29, 1998, I sent a facsimile message to James C. Peacock, III, at (408) 245-9427, requesting that he send to me via facsimile the signature page of the Declaration and Power of Attorney or that he contact me immediately. A copy of said facsimile message

together with a copy of the confirmation of transmission are attached hereto as Exhibit A. To date, I have not received a response of any kind.

3. On January 5, 1998, I forwarded a letter to Celso S.J. Bagaoisan, via Federal Express, to 4441 Pomponi Street, Union City, CA 94587. I enclosed therewith a Declaration and Power of Attorney for his signature in connection with the above-referenced application, and a return self-addressed, postage prepaid Federal Express envelope. A copy of said letter is attached hereto as Exhibit B. On January 29, 1998, I left a voice message for Celso S.J. Bagaoisan at his residence telephone (510) 471-0747. To date, I have not received a response of any kind.

4. On January 7, 1998, I forwarded a letter to John P. Shanahan, via Federal Express, to 1530 Barn Owl Place, Santa Rosa, CA 95409. I enclosed therewith a Declaration and Power of Attorney for his signature in connection with the above-referenced application, and a return self-addressed, postage prepaid Federal Express envelope. A copy of said letter is attached hereto as Exhibit C. On January 29, 1998, I telephoned John P. Shanahan at his residence (707) 579-2620, and there was no answer. To date, I have not received a response of any kind.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of this application or any reissue patent issued thereon.

Executed this 29th day of January, 1998, at Palo Alto, California

By: Nita J. Miller
Nita J. Miller

surrounding the unavailability of the aforementioned inventors, and a list of the last known addresses of the unavailable inventors below.

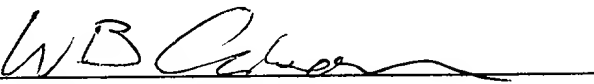
Last known addresses and telephone numbers of non-signing joint inventors:

Celso S. J. Bagaoisan
4441 Pomponi Street
Union City, California 94587
(510) 471-0747

P. Shanahan
1 Barn Owl Place
San Jose, CA 95409
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James C. Peacock, III
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Respectfully submitted,

By: 
William B. Anderson
Attorney for Applicants
Registration No. P41,585

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WBA:njm

HEWM #65074